

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1-13 and 52-53 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1 and 3 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

This rejection is obviated by the amendments to claims 1 and 3 to recite a temperature and pH range. The temperature range recited is supported by the specification in the sentence bridging pages 11 and 12. The pH range recited is supported by the disclosure on page 44 of the specification of a pH range of 5-7, on page 26 that the optimum pH is in an acid pH range, and in Figure 3. Thus, the optimum pH range of 5 to 7, which is within the acid pH range is supported by the specification as filed.

Claims 1-13 have been rejected under 35 U.S.C. 112, first paragraph, because the examiner states that the specification, while being enabling for an isolated non-reducing saccharide-forming enzyme obtainable from *Arthrobacter sp.* S34 (FERM BP-6450) comprising an amino acid sequence as set forth in SEQ ID NO:1; does not reasonably provide enablement for any non-reducing saccharide-forming enzyme obtainable from any biological source or encoded by an DNA, any non-reducing saccharide-forming enzyme comprising an amino acid sequence having at least 57% homology to the amino acid sequence of SEQ ID NO:1, or any non-reducing saccharide-forming enzyme having an amino acid sequence

comprising a part or whole of the amino acid sequence of SEQ ID NOs:1-6. This rejection is respectfully traversed.

Applicants submit that the availability of the microorganism *Arthrobacter sp.* S34 (FERM BP-6450) and the disclosure in the specification do indeed provide enablement for the claimed invention. The specification discloses properties of the microorganism at pages 50-54 and a method for preparing the claimed enzyme by culturing the microorganism at pages 57-63 in detail. Furthermore, the physicochemical properties of the claimed enzyme thus obtained are disclosed at pages 63-69 and 81-82.

In addition, the specification discloses mutants of the microorganism in the paragraph bridging pages 15 and 16. The methods for obtaining such mutants had been well known to the skilled artisan at the time the present invention was made. It is easy for the skilled artisan to screen randomly obtained mutants to find the mutants which produce the claimed enzyme because the physiochemical properties of the claimed enzyme are disclosed in the specification as mentioned above.

The specification also discloses at pages 82-85 the methods for preparing the claimed enzyme based on the DNA which encodes the claimed enzyme derived from *Arthrobacter sp.* S34 (FERM BP-6450) utilizing recombinant DNA techniques. Since the specification discloses the amino acid sequence of a preferred embodiment of the claimed enzyme as well as the DNA, it should be quite easy for the skilled artisan to prepare the claimed enzyme using recombinant DNA techniques.

With regard to the enzyme comprising an amino acid

sequence having at least 57% homology to the amino acid sequence of SEQ ID NO:1 and the enzyme having an amino acid sequence comprising a part or whole of the amino acid sequence of SEQ ID NOs:1-6, applicants believe that one of skill in the art can obtain them with only routine experimentation by screening various mutants relying on the physicochemical properties of the enzyme as disclosed at pages 63-69 and 81-82. Applicants therefore submit that the specification provides an enabling disclosure for the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 9 and 10 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not describe in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The examiner states that the microorganism *Arthrobacter sp.* S34 (FERM BP-6450) is required to practice the claimed invention and that the microorganism must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. The examiner holds that it is not apparent if the *Arthrobacter sp.* S34 (FERM BP-6450) or source materials to make *Arthrobacter sp.* S34 (FERM BP-6450) are both known and readily available to the public. Therefore, a deposit at a recognized depository must be made for enablement purposes.

Attached hereto is a copy of the deposit receipt for the deposit of the microorganism *Arthrobacter sp.* S34 (accession

no. FERM BP-6450) under the Budapest Treaty and an English translation thereof. An executed declaration of biological materials deposit will be filed in a supplemental response to obviate this rejection.

Claims 1-8, 11, and 13 have been rejected under 35 U.S.C. §102(b) as being anticipated by Kubota et al. The examiner incorrectly states that Kubota discloses a non-reducing saccharide-forming enzyme having an optimum temperature of over 40°C but below 60°C. From page 4, lines 4-5, page 8, lines 19-24, and Figures 1 and 2 of Kubota, it is clear that the optimum temperature of the enzyme disclosed in Kubota is in the range of 35°C-40°C. By contrast, the optimum temperature of the presently claimed enzyme is over 40°C. Accordingly, the presently claimed enzyme cannot be anticipated by Kubota's enzyme.

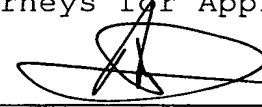
Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

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F:\S\SUMA\Yamamoto16A\pto\amendment.wpd

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Claims 1, 3 and 13 have been amended as follows:

1(Once-Amended). A non-reducing saccharide-forming enzyme, which forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate, and which has an optimum temperature of ~~in a medium temperature range~~ over 40°C.

3(Once-Amended). The enzyme of claim 1, which has an optimum pH in an acid pH range from 5 to 7.

13(Once-Amended). The non-reducing saccharide-forming enzyme of claim 1, which has the following physicochemical properties:

(1) Action

Forming a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysates having a degree of glucose polymerization of 3 or higher;

(2) Molecular weight

About 75,000  $\pm$  10,000 daltons on sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE);

(3) Isoelectric point (pI)

About 4.5  $\pm$  0.5 on isoelectrophoresis using ampholyte;

(4) Optimum temperature

About 50°C when incubated at pH 6.0 for 60 min;

(5) Optimum pH

About 6.0 when incubated at 50°C for 60 min;

(6) Thermal stability

Stable up to a temperature of about 55°C when incubated at pH 7.0 for 60 min; and

(7) pH stability

Stable at pHs of about 5.0 to about 10.0 when incubated at 4°C for 24 hours.

国際様式 INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

下記国際寄託当局によって規則7.1に従い  
発行される。

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this  
page.

原寄託についての受託証

氏名 (名称) 株式会社 林原生物化学研究所  
代表取締役社長 林原 健

寄託者

殿

あて名 〒

岡山県岡山市下石井1丁目2番3号

1. 微生物の表示	
(寄託者が付した識別のための表示) アルスロバクター スビーシーズ (Arthrobacter sp.) S34	(受託番号) FERM BP- 6450
2. 科学的性質及び分類学上の位置	
1 欄の微生物には、次の事項を記載した文書が添付されていた。  <input checked="" type="checkbox"/> 科学的性質 <input checked="" type="checkbox"/> 分類学上の位置	
3. 受領及び受託	
本国際寄託当局は、平成10年 8月 6日(原寄託日)に受領した1欄の微生物を受託する。	
4. 移管請求の受領	
本国際寄託当局は、 年 月 日(原寄託日)に1欄の微生物を受領した。 そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。	
5. 国際寄託当局	
<p>通商産業省工業技術院生命工学工業技術研究所</p> <p>National Institute of Bioscience and Human-Technology Agency for Industrial Science and Technology</p> <p>名称: 大箸 信一 所長 Dr. Shinichi Oshichi Director-General</p> <p>あて名: 日本国茨城県つくば市東1丁目2番3号 (郵便番号305-8566) 1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken 305-8566, JAPAN</p>	
平成10年(1998) 8月 6日	

(English Translation)  
INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF  
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page.

Applicant: 2-3, 1-chome, Shimoishii, Okayama-shi, Okayama 700-0907, Japan  
KABUSHIKI KAISHA HAYASHIBARA SEIBUTSU KAGAKU KENKYUJO  
Representative President Ken Hayashibara, Esq.

**I. IDENTIFICATION OF THE MICROORGANISM**

Identification reference given by the DEPOSITOR:

*Arthrobacter* sp. S34

Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:

FERM BP-6450

**II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION**

The microorganism identified under I above was accompanied by:

- ☒ a scientific description
- ☒ a proposed taxonomic designation

(Mark with a cross where applicable)

**III. RECEIPT AND ACCEPTANCE**

This International Depositary Authority accepts the microorganism  
identified under I above, which was received on August 6, 1998.

**IV. International Depositary Authority**

Name: NATIONAL INSTITUTE OF BIOSCIENCE AND HUMAN-TECHNOLOGY  
AGENCY OF INDUSTRIAL SCIENCE AND TECHNOLOGY

Director: Dr. Shinichi Ohashi, Director-General

Address: 1-3, Higashi, 1 chome, Tsukuba-shi, Ibaraki-ken 305-8566, Japan

Date : August 6, 1998





国際様式

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

特許手続上の微生物の寄託の国際的承認  
に関するブタベスト条約

下記国際寄託当局によって規則10.2に従い  
発行される。

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page.

生存に関する証明書

氏名 (名称) 株式会社 林原生物化学研究所  
代表取締役社長 林原 健

申請者

あて名 〒

岡山県岡山市下石井1丁目2番3号

殿

1. 寄託者		2. 微生物の表示	
氏名 (名称) 株式会社 林原生物化学研究所 代表取締役社長 林原 健  あて名 〒 岡山県岡山市下石井1丁目2番3号		受託番号:  FERM BP- 6450  受託の日:  平成10年 8月 6日	
3. 生存試験の結果			
2 株の微生物の生存について 平成10年 8月 31日 に試験を実施した結果、当該微生物は、 <input checked="" type="checkbox"/> 生存していた。 <input type="checkbox"/> 生存していなかった。			
4. 生存試験に際して使用した条件 (結果が否定的である場合のみ)			
<input type="checkbox"/> 微生物条件記録書の写し 1通			
5. 国際寄託当局			
通商産業省工業技術院生命工学工業技術研究所  名称: National Institute of Bioscience and Human-Technology Agency for Industrial Science and Technology  所長 大箸 信  あて名: 日本国茨城県つくば市東1丁目1番3号 (郵便番号305-8566) 1-3, Higashi 1-chōme Tsukuba-shi Ibaraki-ken 305-8566, JAPAN  平成10年 (1998) 9月 8日			

(English Translation)  
INTERNATIONAL FORM

**BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR  
THE PURPOSES OF PATENT PROCEDURE  
VIABILITY STATEMENT**

issued pursuant to Rule 10.2 by the INTERNATIONAL  
DEPOSITARY AUTHORITY identified on the following page.

Applicant: 2-3, 1-chome, Shimoishii, Okayama-shi, Okayama 700, Japan  
KABUSHIKI KAISHA HAYASHIBARA SEIBUTSU KAGAKU KENKYUJO  
Representative Ken Hayashibara, Esq.

**I. Depositor**

2-3, 1 chome, Shimoishii, Okayama-shi, Okayama 700, Japan  
KABUSHIKI KAISHA HAYASHIBARA SEIBUTSU KAGAKU KENKYUJO  
Representative President Ken Hayashibara, Esq,

**II. Identification of microorganism**

Accession number given by the International Depositary Authority: FERM BP-6450

Date of the deposition: August 6, 1998

**III. Result of the viability test**

The viability test of the above identified microorganism conducted on August 31, 1998  
resulted to show that it was: (check appropriate item below)

☒ Viable  
☐ Inactive

**IV. Conditions used in the viability test (applicable only in the case of a negative result)**  
(check if applicable)

☐ The conditions record of microorganism.....One copy

**V. International Depositary Authority**

Name: NATIONAL INSTITUTE OF BIOSCIENCE AND HUMAN-TECHNOLOGY  
AGENCY OF INDUSTRIAL SCIENCE AND TECHNOLOGY

Director: Dr. Shinichi Ohashi, Director-General

Address: 1-3, Higashi, 1 chome, Tsukuba-shi, Ibaraki-ken 305-8566, Japan

Date : September 8, 1998